

REMARKS**A. Status of the Claims and Explanation of the Amendments**

Currently, claims 1-20 have been cancelled and claims 21-43 are pending and presented for examination.

Claims 41-43 have been rejected under 35 U.S.C. §112, ¶2 for allegedly being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. The Office Action alleges that there is insufficient antecedent basis for “unforeseen event” in claims 41-43. In response, Applicant has amended claims 41-43 so that the language conforms with that of claim 40. Reconsideration and withdrawal of the objection to claims 41-43 under 35 U.S.C. §112, ¶2 are respectfully requested.

Claims 21-25, 27-28, 31-32, and 35-43 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,161,095 to Brown (“Brown”), in view of U.S. Patent No. 5,642,731 to Kehr (“Kehr”). Claim 26 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown and Kehr, in view of U.S. Patent No. 5,642,731 to Cummings, Jr. (“Cummings”). Claim 29 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown and Kehr, in view of U.S. Patent No. 4,847,764 to Halvorson (“Halvorson”). Claim 30 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown and Kehr, in view of Campbell (Campbell, Sandy “Accordant meets the challenges that rare chronic diseases pose for managed care”, Health Care Strategic Management, August 1996). Claims 33-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brown and Kehr, in view of U.S. Patent No. 5,774,865 to Glynn (“Glynn”).

B. Applicant's Claims Are Not Unpatentable Over the Combination of Brown and Kehr

Applicant respectfully traverses the rejection of claims 21-25, 27-28, 31-32, and 35-43 under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown and Kehr, for the following reasons: (1) the combination of references would impermissibly change the principle of operation of the primary reference (*see* MPEP §2143.01); (2) the references teach away from the combination (*see* MPEP §2145, Subsection X, Part D); and (3) there is no proper motivation to combine references (*see* MPEP §2143.01). Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 21-25, 27-28, 31-32, and 35-43 under 35 U.S.C. §103(a).

1. The Combination of References Impermissibly Changes the Principle of Operation of the Primary Reference

Brown is directed to a network-based system that is designed to help enforce treatment regimen compliance and efficacy. Importantly, because Brown's invention is directed to ensuring compliance with a treatment regimen, it does not allow patients to self-administer drugs, except in accordance with a service provider's previous instructions. In particular, Brown explicitly specifies that “[a] service provider determines a treatment regimen for selected patients 111 and a protocol to be followed by their portable devices 112 to assist the patients 111 in following the treatment regimen” [Brown, col. 4, lines 43-46, emphasis added]. The portable device 112 assists the patients in following a treatment regimen by providing the patient 111 with reminder messages to perform a certain act, such as taking medicine [Brown, col. 5, lines 4-8; and col. 5, lines 10-15; emphasis added]

While the focus of Brown's invention is to help ensure compliance with a service provider's pre-determined treatment regimen, Kehr suggests that patients can take pills at "unscheduled times" [see, e.g., Kehr, col. 4, lines 14-15, and col. 15, lines 10-24]. Patients who take pills at "unscheduled times" (i.e., whenever they feel like it) inherently would violate any treatment regimen pre-determined by a service provider as taught by Brown. Accordingly, the Office Action's suggestion to combine taking pills at "unscheduled times" as taught by Kehr, with the network-based system to ensure treatment regimen compliance, as taught by Brown, is improper because it violates the principle of operation of Brown's network-based system (i.e., enforcing compliance of a service provider-determined treatment regimen).

For at least this reason, the rejection of claims 21-25, 27-28, 31-32, and 35-43 under 35 U.S.C. §103(a) as being unpatentable over Brown, in view of Kehr, should be withdrawn.

2. Brown Teaches Away from the Proposed Combination

As noted above, Brown discloses that a portable device 112 is used to issue "reminder messages" to the patient, so that the patient will perform a certain act [Brown, col. 5, lines 6-8]. The very nature of a "reminder message" implies that the certain act to be performed was already scheduled – one cannot have a reminder to perform an unscheduled act. Accordingly, Brown teaches away from taking pills at unscheduled times, as suggested by Kehr, and it is improper to combine Brown and Kehr.

Furthermore, Brown teaches that in certain embodiments, "a portable device 112 can be coupled to a medication dispenser containing the medication specified by the treatment regimen" [col. 6, lines 17-19]. Moreover, the portable device 112 "controls the medication

dispenser so as to release only the **correct dosage** of the **correct medication** at the **correct time** responsive to the treatment regimen" [Brown, col. 6, lines 19-22, emphasis added]. These embodiments also clearly teach away from taking pills at "unscheduled times" as taught by Kehr.

The rejection of claims 21-25, 27-28, 31-32, and 35-43 under 35 U.S.C. §103(a) as being unpatentable over Brown, in view of Kehr, should be withdrawn.

3. There is No Proper Motivation to Combine Brown and Kehr

In rejecting independent claim 21, the Office Action states the following:

Kehr teaches a personal communication device that is programmed for generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment (see column 15, lines 1-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of providing enhanced patient care by providing greater communication between provider and patient especially with respect to unscheduled treatments as suggested by Kehr (see column 4, lines 14-20 of Kehr).

Applicant, however, has noted above that (1) Brown teaches away from this proposed combination, and that (2) the proposed combination impermissibly changes the principle of operation of Brown's device. For at least these two reasons, the proposed combination of Brown and Kehr is improper. In light of these observations, Applicant respectfully maintains that there is no proper motivation to combine Brown and Kehr, and that the combination of Brown and Kehr must be based on improper hindsight reasoning.

But there is more. As a motivation for the combination of Brown and Kehr, the Office Action alleges that the combination would provide "enhanced patient care by providing greater communication between provider and patient especially with respect to unscheduled

treatments as suggested by Kehr (column 4, lines 14-20 of Kehr).” Applicant has reviewed both Brown and Kehr and does not see where either reference provides a motivation to combine Brown and Kehr in the proposed manner. With respect to Brown, Applicant has already noted above that Brown does not contemplate taking pills at “unscheduled times” because Brown is concerned with ensuring compliance with a treatment regimen determined by a service provider. Thus, Brown cannot and does not provide any motivation to combine its network-based system with Kehr’s suggestion of ingesting pills at “unscheduled times,” as proposed by the Office Action.

Applicant has also reviewed Kehr, including the cited portion of Kehr, and does not see where Kehr provides any motivation for combining any of its teachings with the network-based system of Brown. We turn first to the portion of Kehr cited by the Office Action, which reads as follows:

[a]t other times a patient takes a pill at an unscheduled time. It would be helpful to know if at that time they were having a flare-up of illness symptoms, or generally felt more ill. The present device can answer these questions by providing illness symptom ratings and general health questions at the time of the unscheduled medication taking. No prior art reference can do this. [Kehr, col. 4, lines 14-20].

The Office Action has not established how this portion of Kehr, in and of itself, provides any motivation to combine with the network-based system of Brown. Certainly, based only on these four sentences from Kehr (which do not mention anything about network-based systems, let alone Brown’s network-based system) it is difficult to even imagine the proposed combination of Brown and Kehr, unless one were to resort to improper hindsight reasoning. It is an even further stretch to say that the proposed combination would have been obvious to one of ordinary skill in the art at the time that Applicant’s invention was made. Moreover, the wording of this section of

Kehr seems to imply that Kehr's device **alone** is sufficient for providing "illness symptom ratings and general health questions at the time of the unscheduled medication taking". And if Kehr's device alone is sufficient for these stated purposes, then there is no motivation to go through the additional work of combining with the network-based system as taught by Brown.

Applicant, upon review of other sections of Kehr, does not see where any other section of Kehr provides motivation for the proposed combination. Accordingly, Applicant maintains that the proposed combination is based on impermissible hindsight reasoning.

In summary, the combination of Brown and Kehr is improper for at least three reasons: (1) Brown teaches away from the proposed combination; (2) the proposed combination improperly changes the principle of operation of Brown; and (3) the Office Action has not provided any proper motivation to combine the references. Applicant therefore respectfully requests reconsideration and withdrawal of the rejection of claims 21-25, 27-28, 31-32, and 35-43 under 35 U.S.C. §103(a) as being unpatentable over Brown, in view of Kehr.

C. Applicant's Dependent Claims Are Not Unpatentable Over the Cited References

In addition to the rejections discussed in Part B of this response, the Office Action has rejected Applicant's dependent claims 26, 29, 30, 33 and 34. In the rejection of each of these dependent claims, the Office Action starts with the combination of Brown and Kehr, as applied to the corresponding independent claim, and adds a tertiary reference in an attempt to arrive at all of the claim elements of Applicant's dependent claims. Specifically, the Office Action relies on Cummings for a communications device coupled to a network in rejecting claim 26; on Halvorson for a database that contains a product catalog in rejecting claim 29; on Campbell for a

database that is tailored to the disease hemophilia in rejecting claim 30; and on Glynn for a bar code reader and for software capable of accepting input from a patient in rejecting claims 33-34.

However, Applicant argues above that the combination of Brown and Kehr is improper for several reasons. This impropriety of the Brown/Kehr combination is not alleviated by the addition of the tertiary references, as set forth in the Office Action. Accordingly, the rejection of dependent claims 26, 29, 30, 33 and 34 under 35 U.S.C. §103(a) should be withdrawn as well.

Reconsideration and withdrawal of the rejections of these claims are respectfully requested.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

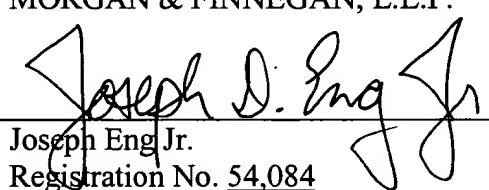
The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 4297-4017. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 4297-4017. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
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